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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/622,583	10/13/00	CAROSELLA E	195707USOPCT

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EXAMINER	
CHUNDURU, S	
ART UNIT	PAPER NUMBER
1656	6

DATE MAILED: 05/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/622,583	CAROSELLA ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *13 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *1 and 4-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☑ ~~Notice~~ of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

1. The preliminary Amendment (Paper No. 5) filed on October 13, 2000 and Response to restriction requirement (paper No.7) filed on April 27, 2001 have been entered and considered.

2. Original Claims were 1-13. The applicants with traverse elected claims 2 and 3 in Group II (paper No.7, dated 4/27/01).

3. Applicant's election with traverse of claims 2 and 3 in Group II in Paper No. 7 (dated 4/27/01) is acknowledged. The traversal is on the ground(s) that (i) a restriction practice under 35 U.S.C. 121 does not apply for the national stage applications. The applicants are correct on this issue, but it is not found persuasive since according to the European Search Authority claims 1, 3, 4, 5, 7-13 are anticipated and lack special technical feature. Hence the restriction of claims into separate groups is deemed proper. (ii) Further, the traversal is on the ground(s) that a search for a method for HLA-G transcription profile of a solid tumor and a method establishing the HLA-G expression profile in view of selecting a treatment would yield similar information regarding transcription and expression. Applicant argues that expression includes both transcription and protein expression. This argument is true but not convincing because in the instant application the applicants claim the methods to establish the transcription/ expression profiles. The inventions are distinct and a large search burden would be required to search each separate invention. As discussed in the restriction requirement, the methods differ in mode of operation, function and effect. Even different uses of the same profile are distinct if they utilize either different method steps or have different functions or have different effects. Group II, and I for example, which both utilize HLA-G expression profile differ in that Group II requires an antibody labeling of histological sections of solid tumor tissue to detect the expression and

Group I requires mRNA and cDNA preparation to detect the transcription profile. The separate classification (as set forth in the restriction requirement) established in each group requires separate search field and is not required for any other group that is classified in a different class and subclass. Classification is prima facie evidence of burden. Applicant has not provided any evidence, which overcomes this prima facie case, so the separate searches remain burdensome. Hence, the restriction requirement is still deemed proper and is therefore made FINAL.

3. The disclosure is objected to because of the minor informalities:

Specification

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 3 are confusing for referring to the subject matter in the term "and/or". Thus it is unclear how the claims can simultaneously encompass all of these limitations. The claims should refer to the subject matter in the alternative only, the replacement of the term "and/or" with "or" or the addition of dependent claims are suggested.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith JB. (USPN. 5,750,339) and in view of Klein et al. (Israel J.Med.Sci., 32(12): 1238-1243, 1996).

Smith teaches a method for detection of HLA-G transcripts in fetal cells wherein they disclose that fetal cells were contacted with antibodies to cell surface antibodies (labeling cells) and separation of antibody/ antigen complexed fetal cells using magnetic or flow cytometry selection techniques (detection of antigen/antibody complexes) and analyzing HLA-G transcripts in these cells by in situ hybridization technique (see column 5, lines 9-27, column 7, lines 45-67 and column 8, lines 1-64). However, they did not teach HLA-G expression profile of a solid tumor.

Klein et al. teach HLA class I antigen expression in human solid tumors wherein they disclose HLA class I expression by immunohistochemistry (labeling cells of the histological section of tumor tissue) and correlation of immunostaining pattern of HLA class I antigen expression to the developmental stage of the tumors (see page 1239, paragraph 3).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method of HLA-G expression using antibodies as taught by Smith with the method of immunohistochemistry as taught by Klein et al. to the to extrapolate to the application for a method to establish HLA-G transcription profile to achieve expected advantage of establishing the HLA-G expression in solid tumors. The motivation for this would have been an approach to characterize tumor samples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
May 11, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

5/18/01